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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,306	04/01/2004	Emanuela Keller	KELLER, E. ET AL. - 1	8572
25889	7590	07/09/2008		
COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			EXAMINER LAURITZEN, AMANDA L	
			ART UNIT	PAPER NUMBER
			3737	
			MAIL DATE	DELIVERY MODE
			07/09/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/816,306	<b>Applicant(s)</b> KELLER ET AL.	
	<b>Examiner</b> A. LAURITZEN	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2008 and 17 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>17 March 2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

This action is in response to a request for continued examination filed 8 February and a supplemental amendment filed 17 March 2008. Amendments to the claims are not interpreted to introduce new matter.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Applicant's arguments are directed to the difference in the prior art of requiring at least two wavelength measurements (each accompanied by a reference wavelength) and to the invention accomplishing measurement(s) by way of a single signal and single wavelength. It is argued that the primary reference to Pfeiffer et al. requires at least two infrared spectroscopes, but it is pointed out that the claims do not include limitations which exclude measures at two or more wavelengths, nor does any claim limitation exclude measures from more than one signal. Applicant additionally points out that the system of Pfeiffer et al. is a multi-channel apparatus, but again it is not clear what specific claim limitation(s) exclude an apparatus of this nature from being used in practice of the method of the invention because it is not specifically recited that only a single wavelength within the NIR range is being utilized in the method of the invention.

Applicant has amended claims to specifically recite that a concentration is determined from a non-pulsatile (dc) component of a signal and that blood flow is determined from a non-pulsatile component by incrementally varying a mean transit time. To meet this limitation(s), Examiner presents new grounds of rejection in view of Dekker (US 6,709,402).

## **DETAILED ACTION**

### ***Priority***

1. Applicant's claim for the benefit of a prior-filed German Application No. 103 15 574.0 filed Apr. 5, 2003 is acknowledged under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4, 7-9, 11, 12, 13, 16, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeiffer et al. (US 6,223,069) in view of Dekker (US 6,709,402).

Pfeiffer et al. disclose a device for measuring cerebral blood flow using an injection of indocyanine green as an indicator for NIRS (abstract; col. 2, lines 6-7). Specifics of the method include emitting and detecting radiation at first and second locations, as measurement is cited at both hemispheres of the brain (col. 2, lines 44-45). The arterial and cerebral dye curves correspond to inflow and outflow functions, with the outflow function being expressed by a convolution integral (col. 5, lines 1-10). Optical density is monitored with respect to time (effectively the derivative) in the tissue (col. 4, lines 34-37). The mean transit time is specified in determination of the inflow function and "varying rates" imply variation of transit times (col. 5, lines 40-49). The process of determining the inflow function is deemed iterative (col. 5, line

19). It is additionally disclosed that the blood flow and mean transit time are utilized to determine the volume of blood (col. 8, lines 13-15), with a flow parameter by definition being a quotient of volume and time (col. 5, line 33 for ml/min for a flow transport function). The auxiliary variable of the integral provides a scaling factor (col. 5, lines 1—11). The method includes iterative determination of the inflow function that is represented as a sum of a finite number of functions that are similar in form to the transport function (col. 5, line 38 for the transport function and line 52 for the summation).

Pfeiffer et al. disclose all features of the invention as substantially claimed, as detailed above, but do not delineate that the non-pulsatile signal component is used in determination of concentration and blood flow, but in the same field of endeavor, Dekker teaches pulsatile and non-pulsatile signal component extraction, with a concentration determined from the non-pulsatile (dc) component (col. 13, line 65 - col. 14, line 11). It would have been obvious to one of ordinary skill in the art at the time of invention to obtain concentration, flow and volume measures from pulsatile and non-pulsatile signal components.

3. Claims 2, 5, 6, 10, 14, 15, 17, 18, 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeiffer et al. '069 in view of Dekker '402, applied to claim(s) above, further in view of Boas (US 6,516,214).

Pfeiffer et al. as appended by Dekker includes all features of the invention as substantially claimed but is silent with regard to steps of using a threshold value, extrapolation of a scaled inflow function, and applying a locally increased contact pressure, but in the same field of endeavor, Boas discloses establishing a threshold for dye concentration comparison (col. 3, lines 2-7), extrapolating the position from the scaled inflow function for determining the location

Art Unit: 3737

of an ischemic event (col. 3, lines 27-39), and applying contact pressure (see flexible cap 400 with rubber grommets 440 that generates pressure in order to fix the device to the patient's scalp; also col. 10, lines 20-42). It would have been obvious to one of ordinary skill in the art at the time of invention to include the steps of using a threshold value for comparison purposes and extrapolation of data for determining location as taught by Boas with the method of Pfeiffer in order to evaluate an ischemic event (abstract; also col. 3, lines 13-14).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. LAURITZEN whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. L./  
Examiner, Art Unit 3737

A. LAURITZEN  
Examiner  
Art Unit 3737

/Brian L Casler/  
Supervisory Patent Examiner, Art Unit 3737